GEORGIA INSTITUTE OF TECHNOLOGY — OFFICE OF CONTRACT ADMINISTRATION

## PROJECT ADMINISTRATION DATA SHEET

[x] ORIGINAL
[ ] REVISION NO. ____

Project No. E-19-661 (follow-on to E-19-619) DATE: 6/18/81

Project Director: Dr. A. P. Yoganathan School/~~Lab~~ Chemical Engineering

Sponsor: American Heart Association, Georgia Affiliate; Atlanta, GA 30324

Type Agreement: Grant dated 5/29/81

Award Period: From 7/1/81 To ~~6/30/82~~ 7/31/82 (Performance) 8/1/82 (Reports)

Sponsor Amount: $11,550 Contracted through:

Cost Sharing: None GTRI/~~GIT~~

Title: Grant-In-Aid for Fluid Dynamic Studies of Prosthetic Heart Valves

ADMINISTRATIVE DATA OCA CONTACT Duane Hutchison X4820

1) Sponsor Technical Contact:

2) Sponsor Admin./Contractual Contact: Ms. Ann Angelo, Program Director; American Heart Association, Georgia Affiliate; 2581 Piedmont Road, N.E., P. O. Box 13589, Atlanta, Georgia 30324 (404) 261-2260

Reports: See Deliverable Schedule Security Classification: None

Defense Priority Rating: None

RESTRICTIONS

See Attached N/A Supplemental Information Sheet for Additional Requirements.

Travel: Foreign travel must have prior approval - Contact OCA in each case. Domestic travel requires sponsor approval where total will exceed greater of $500 or 125% of approved proposal budget category.

Equipment: Title vests with GIT

COMMENTS:

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GEORGIA INSTITUTE OF TECHNOLOGY | OFFICE OF CONTRACT ADMINISTRATION

# SPONSORED PROJECT TERMINATION SHEET

Date 8/24/82

**Project Title:** Grant In Aid For Fluid Dynamic Studies of Prosthetic Heart Valves

**Project No:** E-19-661

**Project Director:** Dr. A. P. Yoganathan

**Sponsor:** American Heart Association

**Effective Termination Date:** 7/31/82

**Clearance of Accounting Charges:** 9/1/82

**Grant/Contract Closeout Actions Remaining:**

- [x] Final Invoice and Closing Documents
- [ ] Final Fiscal Report
- [x] Final Report of Inventions
- [x] Govt. Property Inventory & Related Certificate
- [ ] Classified Material Certificate
- [ ] Other ______

**Assigned to:** Chemical Eng. (School/~~Laboratory~~)

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FORM OCA 10:781

E 17-661

AMERICAN HEART ASSOCIATION-GEORGIA AFFILIATE

FLUID DYNAMIC STUDIES OF PROSTHETIC HEART VALVES

(GRANT-IN-AID)

FINAL REPORT (7/1/81 - 6/30/82)

I. Principal Investigator: Professor A. P. Yoganathan

Georgia Tech

Collaborator: R. H. Franch, M.D.

Emory University Medical School

II. Project Report

(a) Even after 20 years of experience the problems associated with valve prostheses have not been totally eliminated. Some of these important problems, such as thrombus formation, hemolysis, tissue overgrowth and damage to the endothelial lining of the vessel wall adjacent to the valve are directly related to the fluid dynamics associated with the various valves. Detailed in vitro fluid dynamic studies of bioprostheses, the newest designs of mechanical and polymeric heart valves, and valve conduits are being conducted. The in vitro laboratory data will be correlated with clinical and pathologic observations. It is hoped that the results of this research will lead to better and longer lasting heart valve prostheses and related cardiovascular products.

Detailed pressure drop, regurgitation and flow visualization studies have been conducted on the following valve designs in both aortic and mitral positions: Starr-Edwards (ball valve), Beall, Bjork-Shiley, Hall-Kaster, Omni-Science, St. Jude, Ionescu-Shiley, Carpentier-Edwards, and Hancock (standard and modified orifice). For most designs more than one valve size was studied. The pulsatile flow studies were conducted in the Georgia Tech pulse duplicator system at a heart rate of 70 beats/min and cardiac outputs of 2.5 to 7.5 ℓ/min. From the pressure drop measurements the effective orifice areas and performance indicies of the different valve designs were calculated as shown below:

$$\mathrm{EOA} = \frac{Q_{rms}}{51.6\sqrt{\overline{\Delta p}}} \qquad \text{—— (1)}$$

$$\mathrm{PI} = \frac{\mathrm{EOA}}{A_{SR}} \qquad \text{—— (2)}$$

where

$\overline{\Delta p}$ = mean systolic or diastolic pressure drop, mmHg

$Q_{rms}$ = root mean square of the flow rate during systole or diastole, $cm^3/s$

EOA = effective orifice area, $cm^2$

$A_{SR}$ = valve sewing ring area, $cm^2$

PI = performance index

The effective orifice area is an index of how well a valve design utilizes its primary or stent orifice area. The performance index is how well a valve utilizes its sewing ring or mounting area. From the above analyses the valves could be arranged in the following order of increasing stenocity: (i) St. Jude, Omni-Science; (ii) Hall-Kaster; (iii) Bjork-Shiley (c-c); (iv) Ionescu-Shiley; (v) Hancock (modified orifice); (vi) Hancock (standard), Carpentier-Edwards, Starr-Edwards (ball valve); (vii) Beall. The performance indicies varied from as high as about 0.72 for the St. Jude and Omni-Science to as low as 0.2 for the Beall disc valve.

During the regurgitation studies, the closing reflux volume and the leakage volume were measured. The valve designs could be listed in the following order increasing regurgitation: (i) Carpentier-Edwards, Hancock (standard and modified orifice); (ii) Beall, Ionescu-Shiley; (iii) Starr-Edwards (ball valve); (iv) Bjork-Shiley, Hall-Kaster; (v) Omni-Science, St. Jude. The porcine tissue valves had regurgitant volumes about 1.0 $cm^3$/beat, while the St. Jude valve had a regurgitant volume of about 10.5 $cm^3$/beat. It was also observed that at a fixed heart rate the total regurgitant volume in $cm^3$/beat remained constant (within experimental error) independent of cardiac output. This, we feel, is an extremely important observation.

Steady and pulsatile flow visualization studies were conducted on the different valve designs. We used a relatively novel technique (using a sheet of laser light) for these studies. The results obtained from the photographs were qualitative as well as semi-quantitative. Examples of the flow visualization work is shown in the enclosed photographs ( 9 ). In these photographs flow is from left to right. A description of the flow fields in the immediate vicinity of the St. Jude aortic valve (27mm) is given below.

Photographs were taken with the leaflets in the vertical position and the thin sheet of laser light parallel to the vertical centerline of the flow section (i.e., almost parallel to the fully open leaflets) at the following locations: (i) centerline of valve (i.e., central orifice); (ii) half between the centerline and flow channel wall (i.e., side orifice); and (iii) adjacent to the flow channel wall. These photographs show the flow through the central and side orifices of the St. Jude aortic valve are jet-like. The photographs taken at the central orifice show flow separation occurring adjacent to the downstream sewing ring. The flow separation appears to reattach to the flow channel wall about 40mm downstream of the valve. The separation region at its widest part takes up about one third to one half of the flow channel cross section along the central orifice of the valve.

The photograph in the side orifice region also shows flow separation. Reattachment, however, occurs closer to the valve sewing ring, about 30 mm downstream. The separation regions in the side orifices are smaller than the separation region occurring in the central orifice, suggesting that more fluid flows through the side orifices compared to the central orifice. Vortices and reverse flow along the flow channel wall are observed in all the flow separation regions. In the photograph adjacent to the flow channel wall the flow field appears to create a small region of separation which reattaches to the wall within a distance of about 20 mm from the valve. Flow recirculation along the wall is also visible in this region.

The laser-Doppler anemometer LDA system was converted from a two beam system to a three beam system. In addition, the LDA system has been interfaced to a PDP 11/03 mini-computer for on-line data collection and analysis. With the three beam system, it is now possible to directly measure the turbulent shear stresses in the immediate vicinity of the valves.

During the year we also conducted a detailed fluid dynamic study on a polymeric trileaflet valve manufactured by Applied Biomedical Corporation. The valve was originally configured for use in a valved conduit. The valve which is manufactured from a polymeric material called Angioflex* was studied in two sizes (21 and 25 mm). A brief description of the results of this study are given below:

The steady and pulsatile flow pressure drops across the 25 mm valves are fairly similar to those measured across 25 mm Ionescu-Shiley pericardial and Bjork-Shiley tilting disc prostheses. The 21 mm Applied Biomedical valve had better pressure drop characteristics compared to the 21 mm Ionescu-Shiley and Carpentier-Edwards tissue valves. In addition, the Applied Biomedical trileaflet valves (25 and 21 mm) had better opening and closing characteristics compared to the tissue valves in current

*Trademark of Applied Biomedical Corp.

clinical use. Steady and pulsatile flow velocity measurements and flow visualization studies indicate that the flow field downstream of the valve is jet-like. The jet type flow leads to turbulent shear stresses on the order of $2 \times 10^3$ and $6 \times 10^3$ dynes/$cm^2$ for the 25 and 21 mm valves, respectively. These sheer stresses are lower than those observed with the corresponding size tissue valves. They are, however, large enough to cause sub-leathal and/or leathal damage to blood elements.

We have also examined Bjork-Shiley, Kay-Shiley, Smeloff, Starr-Edwards and Porcine valve prostheses recovered at surgery or autopsy. Pathologic studies of the mechanical valves revealed thrombus formation and excess fibrotic tissue growth which correlated with regions flow stagnation and flow separation observed _in vitro_. Material analyses on some of the recovered valves are currently in progress. The porcine valves in some cases revealed large amounts of calcification and fibrotic growth on the outflow faces of the leaflets (see attached photograph). _In vitro_ velocity measurements indicate a region of almost stagnant fluid adjacent to the outflow faces of the porcine valve leaflets. It is our opinion that this region of stagnation could encourage calcific, fibrotic and/or thrombotic deposits on the outflow faces of the leaflets. In addition, some of the recovered porcine valve leaflets had varying degrees of cuspal tears. Preliminary work indicates that the concentration of the gluteraldehyde solution, used to prepare the porcine valve can markedly affect the mechanical properties of the leaflets. By using the proper tanning solution it appears it should be possible to enhance the durability and flexibility of the leaflets. Work in this direction is progressing in our laboratory.

For example, during the summer and fall we studied the fluid dynamic characteristics of: (i) #19 Hancock aortic valve, (ii) #23 Hancock mitral valve and (iii) #27 Bjork-Shiley mitral valve. All three valves were recovered during surgery at Emory University Hospital. Both Hancock valves were severely stenosed by calcification and fibrosis of the leaflets. In both valves the muscle shelf leaflets were extremely stiff. The Bjork-Shiley valve had a massive thrombus on its out-flow surface which restricted its opening angle to about $30^{\circ}$. In addition, the disc did not close properly. All three valves were studied in the pulse duplicator under appropriate physiologic conditions. Both Hancock porcine valves created large pressure gradients, even at low cardiac out-puts of 2.0 - 2.5 l/min. It was further observed that all three leaflets of both valves had diminished motion especially the muscle shelf leaflets. The measured in vitro pressure gradients corresponded very well with the clinical gradients measured during catheterization. The Bjork-Shiley mitral valve due to its reduced disc opening angle created larger in vitro pressure gradients than a normally functioning Bjork-Shiley valve. The in vitro gradients corresponded well with the in vivo data. Due to improper closing the valve exhibited larger than normal in vitro regurgitation volumes.

We have constructed models of the various types of pulmonic and aortic valved conduits that are presently commercially available. Detailed fluid dynamic studies are presently in progress. The Carpentier-Edwards, Ionescu-Shiley, Bjork-Shiley and St. Jude valves are being used in the conduit models. The preliminary results from pulsatile flow pressure drop, regurgitation and flow visualization experiments indicate that the mechanical valves are less stenotic. It appears that the St. Jude and Ionescu-Shiley valves have superior fluid dynamic characteristics compared to other mechanical and/or tissue valves that may be used in valved conduits.

Work has just started (during the past few months) on conducting velocity and shear stress measurements in pulsatile flow in the immediate vicinity of the above mentioned valve prostheses. Before we could start the actual measurements we had to write extensive software programs for the on-line collection and analysis of the data on the PDP 11/03 computer system.

(b) Lay Summary

The research is mainly directed toward understanding the fluid dynamic performances of different designs of prosthetic heart valves. In order to evaluate the performances pressure drop, regurgitation, and velocity and shear stress measurements are being conducted in a flow system which duplicates the pulsating flow of the heart. Using sophisticated laser beam techniques, velocity and shear fields are measured in the immediate vicinity of the valves. By knowing the shear and velocity fields, valves can be appropriately designed to minimize damage to the cellular components of blood and to minimize the opportunity for excess tissue growth on and around valve prostheses. The pressure gradient and regurgitant characteristics are two of the major determinants in the clinical use of a given valve design. The overall importance of our research efforts is to understand the advantages and disadvantages of current prosthetic heart valves, so that better and longer lasting valves may be developed. This in turn would be beneficial to the many patients who suffer from valvular heart disease.

III. Collaborators

(a) During the past two years the research group at Georgia Tech has interacted frequently and very productively with R. H. Franch, M.D., cardiologist at Emory University Hospital. We have also interacted with E. C. Harrison, M.D., cardiologist at USC - LA County Medical Center ( Los Angeles) and A. Chaux, M.D., cardiovascular surgeon at Cedars-Sinai Medical Center (Los Angeles). Dr. Franch has been very helpful in obtaining clinical data on valve patients and in examining heart valves recovered during surgery and/or autopsy at Emory University Hospital. Dr. Harrison has been very helpful in supplying us with pathological data on recovered valves from the Los Angeles county area. Dr. Chaux has acted as a general consultant to the project, especially with his clinical experience with the St. Jude Medical bi-leaflet valve prostheses.

(b) The following graduate students at Georgia Tech have worked on the project:

Yi-Ren Woo - PhD Student
Dana Stevenson - PhD Student
Frank Williams - MS Student
Patrick Faughnan - MS Student
Linda Griffith - Undergraduate Student

## IV. Publications

### (a) Abstracts and Presentations

1. Yoganathan, A. P., and Franch, R. H., "In vitro fluid dynamics of tissue bioprostheses," Proceedings 2nd World Congress of Chemical Engineering, Montreal, Canada, October 1981.

2. Yoganathan, A. P., "In vitro flow testing of prosthetic heart valves," Proceedings ASME Winter Annual Meeting, Washington, D. C., November 1981.

3. Yoganathan, A. P., Franch, R. H., and Harrison, E. C., "Clinical pathological problems observed with prosthetic heart valves: Possible relationship to fluid dynamics," Proceedings ASME Winter Annual Meeting, Washington, D. C., November 1981.

4. Stevenson, D. M., Yoganathan, A. P., and Franch, R. H., "Fluid dynamics of tilting (pivoting) disc heart valve prostheses," Paper #109C, presented at the 74th Annual AIChE Meeting, New Orleans, November 1981.

5. Woo, Yi-Ren, Williams, F. P., and Yoganathan, A. P., "In vitro fluid dynamic characteristics of the Applied Biomedical trileaflet valve prostheses," presented at the 28th Heat Transfer and Fluid Mechanics Institute, Sacramento, California, June 1982.

### (b) Publications

1. Stevenson, D. M., Yoganathan, A. P., and Franch, R. H., "The Bjork-Shiley heart valve prostheses: Flow characteristics of the new 70° model," Scandinavian Journal of Thoracic and Cardiovascular Surgery, 16, 1-7 1982.

2. Yoganathan, A. P., Chaux, A., and Gray, R., "Flow characteristics of the St. Jude Prosthetic Valve: An in vitro and in vivo study," accepted for publication in Artificial Organs, February 1982.

3. Yoganathan, A. P., Stevenson, D. M., Williams, F. P., Woo, Y-R, Franch, R. H., and Harrison, E. C., "In vitro fluid dynamic characteristics of the Medtronic-Hall pivoting disc heart valve prosthesis," accepted for publication in Scandinavian Journal of Thoracic and Cardiovascular Surgery, March 1982.

4. Woo, Y-R, Williams, F. P., and Yoganathan, A. P., "In vitro fluid dynamic characteristics of the applied biomedical trileaflet valve prosthesis," submitted to Journal of Biomechanical Engineering, March 1982.

V. Research Continuation

We are actively continuing our research program on the fluid dynamics of prosthetic heart valves. We have been awarded a continuation grant for $11,500 from your organization. With this continuation grant we plan to complete the pulsatile flow velocity and shear stress measurements on different designs of heart valves. In addition, funds are being provided by the School of Chemical Engineering at Georgia Tech to purchase capital equipment for the Bio-Fluid Dynamics Laboratory, and to support graduate student stipends.